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EXAMINER	
LONG, SCOTT	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/534,538	XI ET AL.	
	Examiner	Art Unit	
	SCOTT LONG	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2009 has been entered.

Claim Status

Claims 1-11 and 20-21 are canceled. None of the remaining claims were amended. Claims 12-19 are under current examination.

Priority

This application claims benefit as a 371 of PCT/CN03/00967 (filed 11/14/2003). This application claims benefit from foreign patent application (CHINA) 02149375.8 (filed 11/14/2002). The instant application has been granted the benefit date, 14 November 2002, from foreign patent application (CHINA) 02149375.8.

37 CFR 1.132 Declaration

The examiner acknowledges receipt of the Declaration under 37 CFR 1.132 by Dr. Yongzhi Xi filed on 30 November 2009.

The Declaration under 37 CFR 1.132 filed 29 June 2009 is sufficient to overcome the rejection of claims 12-19 based upon obviousness over Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) in view of Xi et al. (accession number AAK98621, direct submission on 19 July 2001) and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000) as set forth in the last Office action because:

The affiant has sworn that the chicken collage II cDNA sequence provided on 19 July 2001 (Genbank accession number AY046949) is different from the corrected chicken collage II cDNA sequence provided in 2003 and 2006.

Furthermore, the affiant has sworn that the chicken collagen II polypeptide sequences identified in Genbank accession number AAK98621 were not provided by direct submission on 19 July 2001.

The affiant's submission has successfully invalidated Xi et al. (Genbank accession number AAK98621) as prior art.

RESPONSE TO ARGUMENTS

35 USC § 103

The rejection of claims 12-19 under 35 U.S.C. 103(a) as being obvious over unpatentable over Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) in view of Xi et al. (accession number AAK98621, direct submission on 19 July 2001) and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000) is withdrawn in response to the applicant's arguments and/or claim amendments.

The applicant's arguments have been fully considered and are persuasive. The applicant has argued that in view of the Xi Declaration, the Xi reference is not properly considered prior art. After reviewing the Xi Declaration, the examiner concurs with the applicant's view. Accordingly, the pending Obviousness rejection is improper.

Therefore, the examiner hereby withdraws the rejection of claims 12-19 under 35 U.S.C. 103(a) as being obvious over unpatentable over Upholt et al. in view of Xi et al. and further in view of Matsumoto et al.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Matsumoto

Claims 14 and 18-19 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Matsumoto et al (US-6,010,722, issued 4 January 2000).

Instant claims 18-19 are product claims, claimed as a product-by-process. Both claims indicate that the type II chicken collagen is made by the method of claim 17. The method of claim 17 is a method of making recombinant chicken type II collagen using the sequences of SEQ ID NO:1 or SEQ ID NO:2. The specification indicates that SEQ ID NO:1 and SEQ ID NO:2 encode the full length chicken collagen II protein.

Accordingly to MPEP 2113, the examiner should reject claims using the 102/103 rejection, "when the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. *See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985).*" In the instant case, the isolated and purified type II chicken collagen of Matsumoto is such a product.

Claim 14 is directed to a purified chicken type II collagen which is encoded by the isolated nucleic acid molecule of claim 12. Claim 12 is directed to an isolated polynucleotide of SEQ ID NO: 1. The specification indicates that SEQ ID NO:1 encodes

the full length chicken collagen II protein. Matsumoto et al. teach a purified chicken type II collagen protein.

Claim 18 is directed to a composition comprising the separated and purified chicken type II collagen prepared by the method of claim 17 and a pharmaceutically-acceptable vehicle. Matsumoto et al. teach a pharmaceutical preparation comprising chicken type II collagen (col.5, lines 32-33).

Claim 19 is directed to a food or beverage composition, where the food or beverage composition, in addition to comprising the food or beverage, further comprises a chicken type II collagen prepared according to the method of claim 17. Matsumoto et al. teach a food comprising chicken type II collagen (col.7, lines 28-30).

Accordingly, the products of Matsumoto et al. are anticipated by, or in the alternative, obvious over the instant claims.

Vuorio, Young, Nah, Sandell1, Sandell2 and Upholt

Claim 13 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over as being obvious over Vuorio et al. (Nucleic Acids Research. 1982; 10:1175-1192) in view of Young et al. (Nucleic Acids Res. 1984; 12 (10), 4207-4228) in view of Nah et al. (Journal of Biological Chemistry. 1991; 266(34): 23446-23452) and further in view of Sandell et al. (Journal of Biological Chemistry. 1984; 259(12): 7826-7834) [known hereinafter as Sandell1] and further in view of Sandell et al. (Journal of Biological Chemistry. 1983; 258(19): 11617-11621)

[known hereinafter as Sandell2] and further in view of Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329).

Claim 13 is directed to "an isolated polynucleotide of SEQ ID NO:2."

The examiner has included a copy of the 2005 Memo to TC1600 Examiners regarding the proper interpretation of nucleic acid and peptide claims. As per the Memo, the examiner is interpreting claim 13 to mean: an isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO:2. This interpretation permits the examiner to apply any dinucleotide comprised within SEQ ID NO:2 as anticipating SEQ ID NO:2. As all of the cited references encode a portion of type II chicken collagen, all of the cited references anticipate the instant claims.

The specification further indicates that the full length type II chicken collagen cDNA is 4837bp and consists of an open reading frame (ORF) of 4260bp and a 3' nontranslated region of 520bp. The examiner notes that instant SEQ ID NO:2 is 4793bp. The specification inaccurately indicates that SEQ ID NO:2 is the mature chicken collagen II polypeptide (page 12, paragraphs 2-4). The examiner has provided a sequence alignment between the full length type II chicken collagen cDNA as provided by Genbank and instant SEQ ID NO:2. It is clear from the attached alignment that SEQ IDNO:2 and the cDNA for chicken type 2A1 collagen are nearly identical. The differences being (1) SEQ ID NO:2 lacks 44 nucleotides at the 5' end of CCOL2A1 cDNA and (2) that SEQ ID NO:2 has a single nucleotide change which results in a single Threonine to Alanine amino acid mutation at amino acid 24. Both the specification and art indicate that the cDNA for chicken type 2A1 collagen encode a

1420 amino acid protein. Therefore, the differences between the lengths of SEQ ID NO:2 and the cDNA for chicken type 2A1 collagen and 4260bp needed to encode a 1420 protein is due to both 5' and 3' untranslated nucleotides.

Numerous artisans submitted sequence data providing sequence for the exons which comprise the cDNA sequence of chicken type 2A1 collagen. By the time the applicant submitted SEQ ID NO:2, all the nucleotides of this sequence were known, with the exception of the point mutation resulting in a T24A mutation within the collagen polypeptide. As the genomic and cDNA sequences submitted to GenBank by the applicant in association with subsequent publication of their work on molecular cloning, characterization and localization of chicken type II procollagen gene has not maintained this anomalous mutation, the examiner presumes that the specification contains a typographical error. In addition, instant SEQ ID NO:3, does not contain the T24A mutation. Therefore, the examiner is further persuaded that nucleotide 70 of SEQ ID NO:2 is a typographical error. In addition, the applicant is on record (see various 1.132 Declarations by Dr. Xi) that the earliest submission to Genbank of the polynucleotide sequences encoding type II chicken collagen contained sequence differences from the final submission. The examiner presumes that instant SEQ ID NO:2 contains such a (typographical) error.

The cited references provided polynucleotide sequences for chicken type 2A1 collagen cDNA to the publicly available database, Genbank. All of the references are prior art to the instant application. Each of the references provide different portions of

the cDNA sequence. Accordingly, the examiner views the cited art as obvious over instant claim 13.

If the applicant decides that cited art has not provided for the full sequence of SEQ ID NO:2., the examiner respectfully requests a precise indication of the deficient region. As far as the examiner can determine, all sequences taught in SEQ ID NO:2 were publicly available at the time of filing.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to provide a cDNA sequence for type II chicken collagen.

The person of ordinary skill in the art would have been motivated to compile the existing sequence data into a full-length coding sequence for type II chicken collagen, because the art, having knowledge of the (commercial and scientific) value of this sequence would work towards providing a complete cDNA sequence. Many of the references cited reflect overlapping authorship, demonstrating the quest for this sequence.

An artisan would have expected success, because all the data was of record.

Therefore the sequence Vuorio in view of Young in view of Nah and further in view of Sandell1 and further in view of Sandell2 and further in view of Upholt would have been *prima facie* obvious over the sequence of the instant application.

Vuorio, Young, Nah, Sandell1, Sandell2, Upholt & Matsumoto

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vuorio et al. (Nucleic Acids Research. 1982; 10:1175-1192) in view of Young et al.

(Nucleic Acids Res. 1984; 12 (10), 4207-4228) in view of Nah et al. (Journal of Biological Chemistry. 1991; 266(34): 23446-23452) and further in view of Sandell et al. (Journal of Biological Chemistry. 1984; 259(12): 7826-7834) [known hereinafter as Sandell1] and further in view of Sandell et al. (Journal of Biological Chemistry. 1983; 258(19): 11617-11621)) [known hereinafter as Sandell2] and further in view of Upholt et al. (PNAS. April 1986; Vol.83: 2325-2329) as applied to claim 13 above, and further in view of Matsumoto et al (US-6,010,722, issued 4 January 2000).

The teachings of Vuorio, Young, Nah, Sandell1, Sandell2, and Upholt are described above in a previous 35 USC 103(a) rejection. These references provide the polynucleotide sequence for type II chicken collagen cDNA. SEQ ID NO:2 is a polynucleotide sequence for type II chicken collagen cDNA.

Furthermore, as the examiner can interpret "producing a chicken type II collagen" as producing a fragment of chicken type II collagen, the examiner can apply each of Vuorio, Young, Nah, Sandell1, Sandell2, and Upholt as providing the necessary polynucleotide sequences to produce "a chicken type II collagen."

Matsumoto teach methods of producing recombinant type II chicken collage using recombinant host cells comprising expression vectors comprising a polynucleotide sequence for type II chicken collagen cDNA. These teachings correspond to instant claims 15-17.

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to produce recombinant type II chicken collagen using

recombinant host cells comprising expression vectors comprising a polynucleotide sequence for type II chicken collagen cDNA.

The person of ordinary skill in the art would have been motivated to produce recombinant type II chicken collagen, because Matsumoto recognized the commercial and scientific value of this molecule as a food and drug.

An artisan would have expected success, because all the data and methods are of record and practiced by skilled artisans

Therefore the expression vectors, recombinant host cells and methods of making recombinant type II chicken collagen as taught by Vuorio in view of Young in view of Nah and further in view of Sandell1 and further in view of Sandell2 and further in view of Upholt and further in view of Matsumoto would have been *prima facie* obvious over the products and methods of the instant application.

Claim Rejections - 35 USC § 112, 1st (Enablement)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The Court in *Wands* states: "Enablement is not precluded by the necessity for some 'experimentation.'" Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a prima facie case is discussed below.

NATURE OF THE INVENTION

The instant invention is directed to a method for producing a chicken type II collagen comprising transforming a suitable host cell by the recombinant expression vector of claim 16; culturing the host cell in a suitable culture medium and under appropriate culture conditions; and separating and purifying the chicken type II collagen from the culture medium, the cells, or the medium and the cells. The vector of claim 16 comprises either polynucleotide SEQ ID NO:1 or SEQ ID NO:2.

GUIDANCE PROVIDED AND KNOWLEDGE IN THE ART

The specification indicates that both SEQ ID NO:1 encode full length type II chicken collagen.

The examiner has performed sequence alignments between the cDNA for chicken type 2A1 collagen (col2a1) and each of SEQ ID NO:1 and 2.

The protein translated from SEQ ID NO:1 has extremely low identity to the chicken type 2A1 collagen polypeptide. As the art recognizes that type II collagen is highly conserved among vertebrates, the examiner concludes that the instant method is not enabled for producing "a chicken type II collagen," when it is practiced using polynucleotide SEQ ID NO:1. The examiner has provided an alignment of the chicken collagen type II polypeptide sequence with protein sequences based upon all three 5'-3' frame translations of SEQ ID NO:1. It is very clear that SEQ ID NO:1 does not encode the chicken collagen protein, type II. Therefore, no method of making recombinant chicken collagen II is enabled, using instant SEQ ID NO:1.

It is clear from the attached alignments that SEQ IDNO:2 and the cDNA for chicken type 2A1 collagen are nearly identical.

The specification indicates that the full length type II chicken collagen cDNA is 4837bp and consists of an open reading frame (ORF) of 4260bp and a 3' nontranslated region of 520bp. The examiner notes that instant SEQ ID NO:2 is 4793bp. The specification inaccurately indicates that SEQ ID NO:2 is the mature chicken collagen II polypeptide (page 12, paragraphs 2-4). The examiner has provided a sequence

alignment between the full length type II chicken collagen cDNA as provided by Genbank and instant SEQ ID NO:2. It is clear from the attached alignment that SEQ ID NO:2 and the cDNA for chicken type 2A1 collagen are nearly identical. The differences being (1) SEQ ID NO:2 lacks 44 nucleotides at the 5' end of Chicken COL2A1 cDNA and (2) that SEQ ID NO:2 has a single nucleotide change which results in a single Alanine to Threonine amino acid mutation at amino acid 24. Both the specification and art indicate that the cDNA for chicken type 2A1 collagen encode a 1420 amino acid protein. Therefore, the differences between the lengths of (1) SEQ ID NO:2 and (2) chicken type 2A1 collagen cDNA and (3) the 4260bp needed to encode a 1420 protein is due to both 5' and 3' untranslated nucleotides.

Numerous artisans submitted sequence data providing sequence for the exons which comprise the cDNA sequence of chicken type 2A1 collagen (Nah et al., Young et al., Sandell et al., and Upholt et al). By the time the applicant submitted SEQ ID NO:2, all the nucleotides of this sequence were known, with the exception of the point mutation resulting in a A24T mutation within the collagen polypeptide. As the genomic and cDNA sequences submitted to GenBank by the applicant in association with subsequent publication of their work on molecular cloning, characterization and localization of chicken type II procollagen gene has not maintained this anomalous mutation, the examiner presumes that the instant specification contains a typographical error. In addition, instant SEQ ID NO:3, does not contain the A24T mutation. Therefore, the examiner is further persuaded that nucleotide 70 of SEQ ID NO:2 is a typographical error. Furthermore, the applicant is on record (see the various

Declarations by Dr. Xi), that some of the initial sequences submitted to GenBank were later retracted and changed. The examiner presumes that at the time of filing, some of these (typographical) errors were included in the instant specification.

If the alleged typographical error is not a mistake, then the examiner concludes that despite the high level of similarity between the cDNA sequence of chicken type 2A1 collagen and SEQ ID NO:2, the consequence of expressing a polynucleotide sequence having an altered amino acid sequence from the polypeptide sequence of the known chicken type 2A1 collagen could result in uncertainty in the process of making the chicken collagen. Should the applicant acknowledge that nucleotide 70 of SEQ ID NO:2 contains a typographical error, then the examiner will view the specification as enabling for producing recombinant type II chicken collagen using SEQ ID NO:2.

Therefore, the claimed method necessitates further experimentation and the specification does not provide sufficient guidance on how to make and use the claimed method.

CONCLUSION

In conclusion, given the breadth of the claims and the limited scope of the specification, an undue quantity of experimentation is require to make and use the instantly claimed method for producing a recombinant chicken type II collagen.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

Claim 14 is directed to a purified chicken type II collagen which is encoded by the isolated nucleic acid molecule of claim 12. Claim 12 is directed to an isolated polynucleotide of SEQ ID NO:1.

The examiner has provided an alignment of the chicken collagen type II polypeptide sequence with protein sequences based upon all three 5'-3' frame translations of SEQ ID NO:1. It is very clear that SEQ ID NO:1 does not encode the chicken collagen protein, type II.

While claim 14 is directed to a purified type II chicken collagen protein, the claim further narrows the scope of that protein by the limitation that it is encoded by SEQ ID NO:1. Because SEQ ID NO:1 does not encode a type II chicken collagen protein, the examiner views this as evidence that that claim 14 fails to correspond in scope with that which applicant(s) regard as the invention. This is in direct contradiction to the specification which indicates that SEQ ID NO:1 encodes the full length type II chicken collagen protein.

Claim Rejections - 35 USC § 101 and § 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 12, 15 and 16 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

When determining whether an applicant has described the utility of invention, one has to determine whether the claimed invention has a well-established utility. If not, it must be established that the application has made an assertion of specific, substantial and credible utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for use. In contrast to general utility, a specific utility will be specific to the claimed subject matter. A substantial utility defines a real world utility of the invention, while utilities that require or constitute carrying out further research to identify or reasonably confirm a real world context or use are not considered substantial utility (see utility guidelines, in Federal Register 5 January 2001, Volume 6, Number 5, Pages 1092-1099).

The specification teaches that the present invention relates to the discovery, identification and characterization of a novel polynucleotide, SEQ ID NO:1 that encodes

type II chicken collagen. However, SEQ ID NO:1 does NOT encode type II chicken collagen. The examiner has included a sequence alignment between the Genbank protein sequence for Chicken Collagen, type 2A1 and 5'-3' translations of SEQ ID NO:1 for each of the three frames. It is clear that SEQ ID NO:1 does not encode chicken collagen, type 2A1, as suggested by the specification.

A novel nucleic acid sequence has no utility. The specification does not disclose the function of SEQ ID NO:1. Without such knowledge, one would not know how to use the polynucleotide and the encoded protein for a real world utility.

The applicant is referred to the Revised Utility Examination Guidelines published December 21, 1999 in the Federal Register, Volume 64, Number 244, pages 71441-71442 for the required *specific and substantial* utility. "A CLAIMED INVENTION MUST HAVE A SPECIFIC AND SUBSTANTIAL UTILITY. THIS REQUIREMENT EXCLUDES 'THROW-AWAY,' 'UNSUBSTANTIAL,' OR 'NONSPECIFIC' UTILITIES," (column 3, 3rd paragraph of 71441). According to the guidelines, utilities that require or constitute carrying further research to identify or reasonably confirm a "real world" context of use are not *substantial* utilities.

Furthermore, the disclosed vectors and host cells are only useful for the production of more polynucleotide or of polypeptides encoded thereby, and for further research. These utilities apply to many unrelated human polynucleotide fragments and are not considered a specific and substantial utility in those instances where the final product, has no disclosed or well-established utility.

In view of the instant specification, the only readily apparent *immediate* utility for the disclosed polynucleotide is characterization of the polynucleotide itself in terms of

map location, possibility of association with a disease gene, sequence of corresponding mRNA, cDNA, and polypeptide, identity of the function for the corresponding polypeptide and variants, etc. The sole immediate utility constitutes research on the claimed product itself (which is a non-statutory utility) in order to determine a specific and substantial statutory utility for the claimed invention. Practice of these disclosed utilities would first require further research on the disclosed sequence itself, i.e. there is no apparent immediate benefit to the public. Brenner v. Manson, 148 USPQ 689, 696 (US SupCt, 1966) noted that "CONGRESS INTENDED THAT NO PATENT BE GRANTED ON A CHEMICAL COMPOUND WHOSE SOLE 'UTILITY' CONSISTS OF ITS POTENTIAL ROLE AS AN OBJECT OF USE-TESTING", and stated, in context of the utility requirement, that "A PATENT IS NOT A HUNTING LICENSE. IT IS NOT A REWARD FOR THE SEARCH, BUT A COMPENSATION FOR ITS SUCCESSFUL CONCLUSION."

Because the claimed invention is not supported by a specific and substantial asserted utility or a well-established utility for the reasons set forth above, credibility of the asserted utility cannot be assessed.

Claims 12, 15 and 16 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Therefore, given the lack of guidance and direction in regard to what the polynucleotides would do and how one would use such, the artisan would be required to exercise undue experimentation in practice of the invention.

Specifically regarding the polypeptide molecule encoded by SEQ ID NO:1, it is not clear what the function of this molecule is or that it has shared functions with members of the collagen family. Since the function of the polypeptide molecule encoded by SEQ ID NO:1 is not understood, it is difficult to conclude that the polypeptide molecule encoded by SEQ ID NO:1 has a shared function with members of the collagen family or that the function has been disclosed in the instant application.

Therefore, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skilled in the art could not practice the invention without undue experimentation as it is broadly claimed.

Conclusion

No claims are allowed.

Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**. The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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